

SEP - 2 1999



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Washington, D.C. 20231

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,209,430

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,209,430, which claims the food additive Sylvacote K and a method of use of the food additive Sylvacote K, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of September 29, 1998 (63 Fed. Reg. 51939). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (4,608 - 86) + 1,382 \\ &= 3,643 \text{ days}\end{aligned}$$

Since the regulatory review period began March 30, 1980, before the patent issued (June 24, 1980), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From March 30, 1980 to June 24, 1980 is 86 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,209,430
Granted	:	June 24, 1980
Original Expiration Date	:	November 24, 1998
Applicant	:	Leon Weber
Owner of Record	:	SCM Corporation
Title	:	Treatment of Inorganic Pigments
Classification	:	260/23H
Product Trade Name	:	Sylvacote K
Term Extended	:	Two years
Expiration Date of Extension	:	November 24, 2000

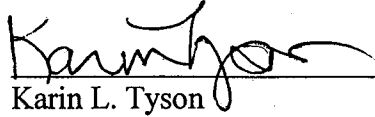
Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23  
2201 South Clark Place  
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

A handwritten signature in dark ink, appearing to read "Karin L. Tyson", is written over a horizontal line.

Karin L. Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: David T. Read  
Acting Director Regulatory Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
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RE: Sylvacote K  
FDA Docket No.: 97E-0294